

Notice of Allowability	Application No.	Applicant(s)	
	09/556,102	DAVEY, CHRISTOPHER T. a	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/21/04.
2. ☒ The allowed claim(s) is/are 12-23,25-29,31-34,36 and 38-45.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>6/21/04</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick Fay on June 21, 2004.

The application has been amended as follows:

Cancel Claims 30 and 37.

Amend Claim 26: Insert underlined limitation

26. Apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion, at least some of the elongated body portion capable of being placed into the body,

a passageway extending through the proximal hub and elongated body portions, the passageway being defined by an inner surface of the sheath, and

a pair of lines extending at least some of the length, and on opposite sides, of the sheath, at least the sheath being separable along the lines; and

(b) a valve comprising

a foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, the foam material being affixed to a portion of the inner surface of the sheath, and

one or more self-sealing slits in the foam material, none of the one or more self-sealing slits in the foam material extend in width to the inner surface of the sheath, the one or more slits capable of allowing the flexible medical device to pass therethrough and sealing around the device.

Amend Claim 39: Insert underlined limitation

39. Apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion,

a passageway extending through the proximal hub and elongated body portions,

and

a pair of lines extending at least some of the length, and on opposite sides, of the sheath, at least the sheath being separable along the lines; and

(b) a valve comprising:

an injected foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, and

one or more self-sealing slits in the foam material, the foam material and the one or more slits serving as a valve in the passageway of the sheath, and wherein none of the one or more self-sealing slits extends in width to an inner surface of the sheath that defines the passageway.

Drawings

2. New corrected drawings are required in this application. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was a medical device with a hub, an elongated body with a passageway and wherein the elongated body had separable lines that allowed the sheath, passageway and valve to separate, as well as self sealing slits in a foam material filling wherein none of the slits extend in width to the inner surface of the sheath or passageway as well as in combination with the other elements or steps of the claim.


The examiner reviewed the appeal brief and in conjunction with the amendments to the independent claims and the remarks in the appeal brief, the examiner could not find or suggest the independent claims.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Matthew DeSanto
Art Unit 3763
June 22, 2004


MICHAEL J. HAYES
PRIMARY EXAMINER